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Kalamazoo, MI 49001  
t: 269 323 7700 f: 800 965 6505  
www.stryker.com

MAY 22 2007

**stryker®**

15063480

**Interventional Pain**

**510(k) Summary**

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|                             |   |
|-----------------------------|---|
| <b>Device Sponsor:</b>      | Stryker Interventional Pain<br>4100 E. Milham Avenue<br>Kalamazoo, MI 49001<br>(p) 269-323-7700<br>(f) 269-324-5412   |
| <b>Registration No.:</b>    | 3005182723  |
| <b>Trade Name:</b>          | Stryker RF Intradiscal Adapter  |
| <b>Common Name:</b>         | Electrosurgical Connecting Cable  |
| <b>Classification Name:</b> | Generator, Radiofrequency Lesion (GXD)  |
| <b>Equivalent to:</b>       | K033981 Smith & Nephew ElectroThermal 20S Spine Generator   |
| <b>Device Description:</b>  | The Stryker RF Intradiscal Adaptor when used with the separately cleared Stryker RF Generator and the separately cleared Smith & Nephew SPINECATH™ Intradiscal Catheter(K993967) and ACUTHERM™ Decompression Catheter or equivalent. The Stryker RF Intradiscal Adaptor is intended for the coagulation and decompression of disc material to treat symptomatic patients with annular disruption of contained herniated discs.  |
| <b>Indications for Use:</b> | The Stryker RF Intradiscal Adapter is intended for the coagulation and decompression of disc material to treat symptomatic patients with annular disruption of contained herniated discs. The Adapter will be used with the previously cleared Stryker Intradiscal RF Generator and catheters such as Smith & Nephew SPINECATH™ & Acutherm™ catheters.  |
| <b>Contraindications:</b>   | <p>The contraindications for the Stryker RF Intradiscal Adapter would be the same as those for the catheter to which it is attached. The contraindications included in the instructions for use for the Smith &amp; Nephew SPINECATH™™ Intradiscal Catheter and ACUTHERM™ Decompression Catheter are:</p> <p><i>Use of the SPINECATH™ Intradiscal Catheter is not appropriate for treating patients who present pain that is suspected to originate from structures other than contained herniated discs, or when free fragments or severe bony stenosis are present. In addition, patients presenting severely degenerative or disrupted discs should be excluded.</i></p> <p><i>and</i></p> <p><i>Use of the Decompression Catheter is not appropriate for treating patients who present pain that is suspected to originate from origins other than herniated discs, or when free fragments or severe spinal stenosis are present. In addition, patients presenting with severely degenerative or disrupted discs should be excluded.</i></p> <p><i>Use of the Smith &amp; Nephew SPINECATH™™ Intradiscal Catheter and ACUTHERM™ Decompression Catheter is appropriate for treating patients</i></p> |

*with herniations of intervertebral discs who would typically undergo automated or laser percutaneous lumbar discectomy.  
Use of the Smith & Nephew SPINECATH™™ Intradiscal Catheter and ACUTHERM™ Decompression Catheter is appropriate for treating patients with herniations of intervertebral discs who would typically undergo automated or laser percutaneous lumbar discectomy.*

**Precautions:**

*Patients taking steroids and patients with pacemakers, lupus, gout, uncontrolled diabetes, Ehlers-Danlos syndrome, prior open capsular procedures, autoimmune disease, or etiologies where their immune systems are compromised require special consideration.*

**Substantial Equivalence  
(SE) Rational:**

The Stryker Intradiscal RF Generator has a similar intended use as:

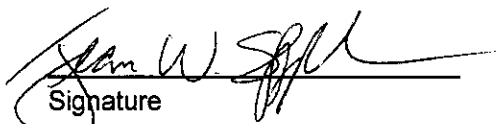
- Smith & Nephew ElectroThermal 20S Spine Generator (K033981)
- Smith & Nephew SPINECATH™ catheters (Oratec K993867)
- Neurotherm NT1000 RF Lesioning System (K052878)

Stryker claims this equivalence because the Stryker RF Intradiscal Adapter has an equivalent intended use, modes of operation, protocols for use, and quality check mechanisms as compared to the predicate devices. Furthermore, the Stryker RF Intradiscal Adapter has equivalent technological characteristics as compared to the predicate devices.

**Safety and Effectiveness:** Based upon the comparison to the predicate devices, the Stryker RF Intradiscal Adapter is substantially equivalent to a legally marketed device.

**Submitted by:**

Jean Sheppard  
Regulatory Analyst

  
Signature

**Date submitted:**

March 8, 2007



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

MAY 22 2007

Stryker Interventional Pain  
% Ms. Jean Sheppard  
Regulatory Analyst  
4100 E. Milham Avenue  
Kalamazoo, Michigan 49001

Re: K063480

Trade/Device Name: Stryker RF Intradiscal Adaptor  
Regulation Number: 21 CFR 882.4400  
Regulation Name: Radiofrequency lesion generator  
Regulatory Class: II  
Product Code: GEI  
Dated: May 10, 2007  
Received: May 11, 2007

Dear Ms. Sheppard:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

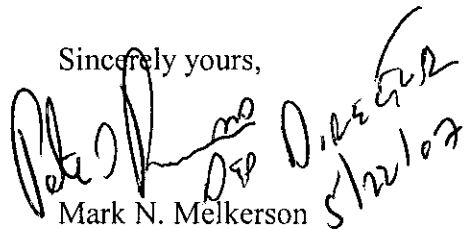
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Ms. Jean Sheppard

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", is written over the typed name. To the right of the signature, there is a handwritten date "5/22/07" and some other illegible markings.

Mark N. Melkerson  
Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K063480

Device Name: **Stryker RF Intradiscal Adaptor**

Indications for Use:

The Stryker RF Intradiscal Adapter is intended for the coagulation and decompression of disc material to treat symptomatic patients with annular disruption of contained herniated discs. The Adapter will be used with the previously cleared Stryker Intradiscal RF Generator and catheters such as Smith & Nephew SPINECATH™ & Acutherm™ catheters.

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF  
NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)

Division of General, Restorative,  
and Neurological Devices

Page 1 of 1

510(k) Number 5/22/02